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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

**Licensing Committee Report**

**Ruth Conroy, Pharm.D., Chair**
**Clarence Hiura, Pharm.D.**
**John Tilley, R.Ph.**
**Richard Benson, Public Board Member**

**Report of March 16, 2005**

# NO ACTION

**Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients**

At the last Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide the foundation to begin the discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and the independent practice of pharmacists as health care professionals.

The committee agreed to address the various issues through its quarterly meetings and was encouraged to develop a proposal sooner than later as the provisions of the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

Based on the discussions at the last meeting, staff drafted a proposal from which the committee could begin addressing the many issues. **(Attachment A)** It was explained the proposal is a means by which to begin the discussions. For better understanding, the concepts were written as statutory changes. The proposal:

- Updates the definition of a pharmacist.

- Revises the definition of a pharmacy to include an "intake/dispensing pharmacy," a "prescription processing pharmacy," an "advice/clinical care pharmacy" and "nonresident pharmacy."
- Acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.
- Updates pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist.
- Requires that a pharmacist who performs cognitive services for California patients be licensed in California.
- Specifies that a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Statutory changes were also made to the pharmacist scope of practice sections, which are technical clean up to make the statutes easier to read and understand. These sections provide for pharmacists' collaborative practice with a physician pursuant to a protocol. There is no change to the scope of practice for pharmacists, the protocol specifications or the emergency contraception drug therapy requirements.

Other changes updated the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Requires that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

In addition, there is a change to require a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management. The board is also given authority to investigate matters related to the performance or provision of cognitive services. The definition of unprofessional conduct for a pharmacist is amended to include those acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services. It also includes the acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct may include acts or omissions that involve the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

There was considerable discussion and concern expressed regarding the draft statutory proposal. The greatest concern raised was the requirement that pharmacists practicing outside of California and providing cognitive services to California patients would be required to be licensed

pharmacists in California even if these services are being provided under the auspices of a nonresident pharmacy permit. Another concern was the proposed requirement that the pharmacist-in-charge for nonresident pharmacies would be required to be licensed California pharmacists. These are major deviations from the current regulatory framework for nonresident pharmacies. There were also questions as to the expanded definitions of pharmacy and the need for these types of facilities to be licensed as pharmacies.

It was noted that the proposal was comprehensive, complex and overwhelming. This proposal will be the focus of roundtable discussions at future Licensing Committee meetings. It is the committee's goal to have a proposal for action at the October board meeting.

**Competency Committee Report**

**Pharmacist Licensure Examination**

The Board of Pharmacy transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. Since February 28, 2005, the board has received 2,778 applications to take the California license exams; 1,341 individuals have become licensed as pharmacists since mid-June and 2,195 individuals have been made eligible to take the licensure examinations; 1,731 individuals have been verified to the National Association of Boards of Pharmacy (NABP) qualified to take the North American Pharmacist Licensure Examination (NAPLEX) for California (includes score transfers); 1,990 CPJE examinations have been administered and 357 have failed the CPJE examinations. Also, 82 regrades of the CPJE have been performed (resulting in no change in score). The CPJE's pass rate is 85 percent.

At this meeting, the board will be given a report on the demographic characteristics and the performance of candidates who have taken the NABPLEX and CPJE, from March 29, 2004 – March 31, 2005. This report will be provided every 6 months.

**Restructure of the Competency Committee**

Last year the Board of Pharmacy agreed with the recommendation from the Licensing Committee to restructure the Competency Committee. The Competency Committee develops and scores the CPJE. The committee is to be restructured into a two-tier structure – a core committee and a group of item writers. The item writers will develop questions for the examination, and the core committee will select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

To activate this restructuring, the board needs additional pharmacists to serve as item writers and committee members. The board is now aggressively recruiting individuals for these important duties. There was an article in the board's January 2005 newsletter, (the first since the restructuring was approved) requesting interested individuals to submit applications. All board members are asked to assist in recruiting for these positions.

The item writers will meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline will be assigned. There will be no other meeting for this group of individuals.

The core committee will be slightly smaller than the current Competency Committee (if the current Competency Committee was fully appointed, there would be 29 members). The new structure is:

| Composition: | 19 members |
|---|---|
| Schools of Pharmacy: 1 member each | 6 members |
| Community Practice: | 6 members |
| Institutional Practice: | 5 members |
| Board Member: | 1 member |
| Inspector: | 1 member |

Attendance of the core committee meetings will be a requirement, and those who miss a certain number of committee meetings each year will be asked to become item writers, where attendance at meetings is not necessary. There will be six two-day meetings annually.

The preference for members of both committees would be for pharmacists who are more recent graduates of pharmacy schools instead of long-term practicing pharmacists, although some experienced pharmacists are also needed. Newer pharmacists are sought because the examination measures practice at the entry level with two years' pharmacist experience, not after 20 years of experience.

Appointment to the committee or as an item writer is an honor and an opportunity to give back to the profession. It is also a good opportunity to learn more about Pharmacy Law. Committee members are paid $30 per hour to perform committee duties.

The board's president appoints the members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814).

**Job Analysis**

The Board of Pharmacy is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline. The board completed its last job analysis in 1999/00.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses will be tallied by the board's examination consultant and analyzed by the Competency Committee in August. A new content outline should be in place by the end of 2005. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

**Administration of the CPJE – New Vendor Contract**

The administration of the CPJE is through Experior Assessments, LLC, at test centers nationwide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because each agency is not required to go out to bid for separate test administration contracts. However, this master contract ends November 30, 2005.

Currently the Department of Consumer Affairs is preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years.

At this time, the tentative RFP release date is April 4th. Review of the responses to the RFP by the evaluation team will be completed by May 4. The new contact should be awarded on June 20, 2005, leaving four months to implement a transition to the new contract before the end of the current contract.

Delays in this process could impact the ability of applicants to take the CPJE after November 30, 2005. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems in December.

**Petition Process for Intern Hours**

For a number of years, pharmacist interns have been required to earn 1,500 hours of intern experience as a requirement for pharmacist licensure. The only exception was for pharmacists licensed in other states who could meet this requirement by providing evidence of licensure and working as a pharmacist for one year in another state.

Last year's board omnibus bill (SB 1913, Chapter 695) contained provisions that moved key intern requirements from board regulations to statutes. At the January 2005 board meeting, the board approved adoption of a related rulemaking to streamline the requirements for earning intern hours. Several changes were made, including one to eliminate a cap of 250 hours on maximum intern hours earned during the first year of pharmacy school. This regulation should be in effect about July 1, 2005.

Since before 1990, the board has had an informal process to allow pharmacists from foreign countries to petition for 600 intern hours for experience they earned in the foreign country as an intern or pharmacist. To petition for the 600 hours, the applicants had to have earned 250 hours of intern experience in California, and provide experience affidavits attesting to their experience in the foreign country. The board used the old intern experience affidavits and required an estimate of how many hours the applicant spent performing the specific duties in the foreign country.

The core of this evaluation was the assumption that the time spent performing the duties on the experience affidavit in the foreign country (e.g., processing prescriptions) would be the same as when performed in California. There was no other validation for this assessment. Members of the Competency Committee would review these experience petitions. Anyone who worked with the individual from the foreign country could sign the affidavit, although the board preferred that a pharmacist do it. Typically fewer than 10 of these petitions were received annually.

The problem is that the petition process outlined above was an underground regulation, and the board cannot continue with this process unless a regulation is promulgated to permit it. The committee did not take any action on this item.

**Accreditation Council for Pharmacy Education (ACPE) Site Visits**

Over the last few months, the ACPE has visited the new schools of pharmacy at Loma Linda University and the University of California San Diego. Chairperson Conroy participated in the review at the Loma Linda School of Pharmacy, and Board Member Schell participated in the review at UCSD. More recently Board Member Dave Fong participated in the pre-candidate review at the University of Touro.

**Meeting Summary of March 16, 2005**
**(Attachment B)**

**Quarterly Status Report on Committee Strategic Objectives for 2004/05**
**(Attachment C)**

# ATTACHMENT A

State of California Department of Consumer Affairs

**Memorandum**

To: Licensing Committee Date: March 3, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Development of Proposal for Pharmacists Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for CA Patients**

At the last Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide the foundation to begin the discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and the independent practice of pharmacists as health care professionals.

There was considerable discussion. The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner than later as the provisions of the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

The following is a summary of the proposed statutory changes to address the issues that were provided to the Licensing Committee at its last meeting. **(Attachment 1)**

***Section 4036*** - This change updates the definition of pharmacist.

***Section 4037*** – This change updates the definition of a pharmacy to include an "intake/dispensing pharmacy", a "prescription processing pharmacy", an "advice/clinical care pharmacy" and "nonresident pharmacy". These pharmacy types are not mutually exclusive. In addition, the definition of pharmacy excludes clinics licensed by the board.

***Section 4050*** – This change acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.

***Section 4051*** – This change is to update pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist. It also requires that a pharmacist who performs cognitive services for California patients be licensed in California. Additionally, it specifies that a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

***Section 4052, 4052.1, 4052.2 and 4052.3*** – These changes are technical clean up of these statutes to make them easier to read and understand. These sections provide for pharmacists' collaborative practice with a physician pursuant to a protocol. There is no change to the scope of practice for pharmacists, the protocol or the emergency contraception drug therapy requirements.

***Section 4112*** – This change updates the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Requires that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

***Section 4113*** – This change updates the requirements for the pharmacist-in-charge and clarifies the board authority to deny an application for a pharmacist-in-charge.

***Section 4125*** – This change requires a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management.

***Section 4207*** – This change includes the board's authority to investigate matters related to the performance or provision of cognitive services.

***Section 4306.5*** – This change adds to the definition of unprofessional conduct for a pharmacist those acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services. It also includes the acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct may include acts or omissions that involve the failure to fully maintain

and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

**Attachment 2** has the background documents from the last meeting that framed the issues.

**Issue 1**
This issue addressed the central processing of prescriptions by California licensed pharmacies. In this situation, Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

In this situation, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

The Licensing Committee didn't have an issue with this situation.

**Issue 2**
In this example, a prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

The central processing facility would fit the definition of proposed Business and Professions Code section 4037(a)(2). It would be considered a prescription processing pharmacy.

**Issue 3**
This scenario is related to a prescription that originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is

filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

It was noted that the out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

The proposal would require that this pharmacy be licensed as a "nonresident pharmacy" and would require that the pharmacist-in-charge and the pharmacists performing drug utilization review and/or any other cognitive pharmacy services for California patients be licensed as well.

**Issue 4**

The fourth example that was presented was about a database for California pharmacies that is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

For this scenario, the out-of-state pharmacy would be required to be licensed in California as a non-resident pharmacy. The pharmacist-in-charge and any pharmacists performing cognitive services would also be required to be licensed in California.

**Issue 5**

The last situation is the new provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/monitoring/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacist related services.

It was noted in the comments provided by the National Association of Boards of Pharmacy (NABP) to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, that NABP was not clear on how states will view the provision of MTMP's across state lines.

The proposal amends Business and Professions Code section 4051, updating the authority and responsibility of pharmacists performing functions related to the practice of pharmacy so as to encompass many of the MTM services. The proposal also requires that a pharmacist performing these functions for California patients be licensed in California. This section of law currently authorizes a pharmacist outside of a licensed pharmacy to provide cognitive services, clinical advice or information and patient consultation.

Medco will be providing a brief presentation on its alternative pharmacy practice site. **(Attachment 3)**

**Attachment 4** is a written comments submitted by Omnicare supporting a concept for requiring a contract between a California licensed pharmacy and its Regional Clinical Center. In addition, Omnicare is requesting that the board move quickly as the Medicare Modernization Act and Part D Medicare are scheduled to being January 2006.

**Proposed Scope of Practice Revisions – Licensing Committee March 16, 2005**

§ 4036. Pharmacist

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of a valid, unexpired pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. The profession of pharmacy may be practiced in diverse settings, including the following:

(1) "Intake/dispensing pharmacy" means an area, place, or premises licensed by the board in which ~~"Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein~~ controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, ~~manufactured~~, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail by personnel licensed by the board.

(2) "Prescription processing pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(3) "Advice/clinical center pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(4) "Nonresident pharmacy" means an area, place, or premises licensed by the board that is located outside this state, that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. It may be any or all of types (a)(1) to (a)(3).

(b) These pharmacy types are not mutually exclusive.

(c) Unless otherwise specified, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to every one of the types in (a)(1) to (a)(4). Unless otherwise specified, each requirement made applicable to any pharmacy by this chapter is applicable to all.

~~(b)~~(d) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(e) "Pharmacy" shall not include any of those clinics listed in Section 4180 or Section 4190.

§ 4050. Professional status

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.

(~~a~~b) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture~~, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(~~b~~d) Notwithstanding any other law, a pharmacist licensed under this chapter may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~.~~

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4052. Power to perform procedures and functions; training

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication~~ drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform ~~the following~~ procedures or functions in a licensed health care facility as authorized by Section 4052.1. ~~in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

(5)~~(A)~~ Perform ~~the following~~ procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2. ~~in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):~~

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

~~(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide cognitive services such as drug utilization review, medication therapy management, consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation, to other health care professionals.

(8)~~(A)~~ Furnish emergency contraception drug therapy ~~in accordance with either of the following~~as authorized by Section 4052.3.~~:~~

(9) Administer immunizations under the supervision of a prescriber.

~~(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~
~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

(b~~e~~) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c~~d~~) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(de) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

§ 4052.1. Performance of procedures or functions in a licensed health care facility; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

§ 4052.2. Performance of procedures or functions authorized by other providers; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

§ 4052.3. Furnishing emergency contraception drug therapy; requirements

(a) Notwithstanding any other provision of law, a pharmacist furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services,

the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.4~~1~~. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4110. Licenses; renewal; transfer; temporary permits; fees

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state,-shall be considered a nonresident pharmacy.
(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(e~~d~~f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter.

(f~~e~~h) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(~~g~~i) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state . The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(~~h~~j) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~

(~~j~~k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4113. Pharmacists-in-charge; designation; responsibilities; notifications

(a) Every pharmacy shall designate a pharmacist-in-charge, and shall not operate as a pharmacy without a designated pharmacist-in-charge. ~~and w~~Within 30 days ~~thereof~~of a new or replacement designation, the pharmacy shall ~~notify~~ submit an application for approval of this designation to the board stating in writing ~~of~~ the identity and license number of ~~that~~ the designated pharmacist-in-charge, ~~pharmacist~~ and the date he or she was designated. The designated pharmacist-in-charge must have a valid, unexpired pharmacist license issued by the board. Where a designated pharmacist-in-charge has been denied a license, had a license revoked, suspended, or placed on probation, or is the subject of an ongoing board investigation into possible unprofessional conduct, the board may prospectively refuse or retroactively withdraw its approval of the designation and require that the pharmacy designate another pharmacist-in-charge.

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge. This duty is separate from and additional to that stated in subpart (a).

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(ed) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(~~d~~e) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4122. Consumer information; posting or written receipts; prices

(a) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the type of services provided by pharmacies. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a nonresident pharmacy, or to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

§ 4125. Quality assurance program

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors and/or inappropriate provision of cognitive services such as prescription review, consultation, drug utilization review, or medication therapy management attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications, or providing cognitive services, so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

~~(c) This section shall become operative on January 1, 2002.~~

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(~~b~~c) As used in this section, and subject to subdivision (~~e~~d), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(~~e~~d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(~~d~~e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(~~e~~f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(~~f~~g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(~~g~~h) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(~~h~~i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(~~i~~j) For licenses referred to in subdivisions (~~f~~g), (~~g~~h), and (~~h~~i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of cognitive services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

§ 4306.5. Acts or omissions constituting unprofessional conduct

(a) Unprofessional conduct for a pharmacist may include:

(1) ~~a~~Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board;

(2) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices and/or with regard to the provision of cognitive services;

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

# ATTACHMENT B

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

# LICENSING COMMITTEE
## Meeting Summary

**DATE:** March 16, 2005

**TIME:** 9:30 p.m. – 12 noon

**LOCATION:** Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621

**BOARD MEMBERS** Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
Richard Benson, Public Member

**STAFF PRESENT:** Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General
Dana Winterrowd, Legal Counsel

## Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m. She announced that committee member John Tilley was unable to attend the meeting.

## Proposed Statutory Changes to the Licensure and Regulation of Clinics

Committee Chair Ruth Conroy reported that the committee was provided an overview of the license process for clinics. A board-licensed clinic is authorized to purchase dangerous drugs at wholesale and owns the dangerous drugs. This means that the authorized prescribers of the clinic can dispense from one central stock. Otherwise, each prescriber must dispense from his/her own stock of dangerous drugs and these drug stocks cannot be commingled.

Consistent with the board's Strategic Plan objective to review all licensing programs, board staff reviewed the board's licensing requirements for clinics. During the review several

inconsistencies between the requirements for nonprofit or free clinics and surgical clinics were noted.

The committee was provided with proposed changes to statute that would streamline the application process, better define who is accountable for the license and make license and regulatory requirements consistent between the two types of clinic licenses.

It was noted that the committee had received comments from Planned Parenthood and the California Primary Care Association. Chair Conroy stated that the matter will be put over until the next meeting for staff to address their concerns regarding the proposal. Comments were also provided from the audience.

**Evaluation and Certification Process for Foreign Pharmacy Graduates by the Foreign Pharmacy Graduate Examination Committee (FPGEC) and the Test of Spoken English (TSE)**

Chairperson Ruth Conroy reported that last year the Board of Pharmacy sponsored an omnibus provision in SB 1913 (Business and Professions Committee, Chapter 695, Statutes of 2004) that requires certification by the FPGEC as an application requirement for foreign educated pharmacists seeking licensure in California. This requirement took effect January 1, 2005. The committee was provided an overview of the certification process. The overview included a memorandum from the National Association of Boards of Pharmacy (NABP) regarding the Test of Spoken English (TSE) that is required of the FPGEC certification process. California has required the TSE since 1991, and amended its regulation to require it of those foreign pharmacy graduates who were FPGEC certified prior to January 1, 1998.

In its memorandum, the NABP expressed concern that a few states are struggling with requests from candidates seeking certification through NABP's FPGEC program to waive the TSE requirement because some candidates have not been able to successfully complete the TSE portion of the English proficiency. The TSE standard recognized by the NABP and California was established through a valid and defensible standard setting process overseen by the National Testing Services (ETS) and competence assessment and psychometric committees. Other health care professions, medicine, nursing, physical and occupational therapists also recognize the passing standard that is accepted by NABP. NABP also noted that it is working with ETS and other health care professions to redesign the English proficiency assessment and perhaps establish one standard for health care professionals that interact and communicate with patients and other health care professionals.

NABP also noted that communication problems are a significant cause of medication errors. NABP stated that a repeated theme at the various NABP/American Association of Colleges of Pharmacy (AACP) District Meetings was the increasingly high number of complaints concerning medication errors that the boards are receiving that are attributed to inadequate communication skills of the pharmacists. Concern was express that Business and Professions Code section 4200.2 (a) requires the board to include in the multi-state pharmacy jurisprudence examination, examination items to demonstrate the candidate's proficiency in patient communication skills. It

was articulated that the only way the board can test a candidate's proficiency in this area is by administering an oral examination.

It was discussed that the board is testing a candidate's proficiency in patient communication skills through multiple-choice questions. This is an acceptable method of testing consistent with the law and approved by the Office of Examination Resources for the Department of Consumer Affairs. To require an English proficiency test of all candidates would require a statutory change.

It was suggested that a representative from ETS attend a future board meeting to explain the TSE.

**Competency Committee Report**

**Pharmacist Licensure Examination**

Assistant Executive Officer Virginia Herold reported that the board transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. Since February 28, 2005, the board has received 2,778 applications to take the California license exams; 1,341 individuals have become licensed as pharmacists since mid-June and 2,195 individuals have been made eligible to take the licensure examinations; 1,731 individuals have been verified to the NABP as qualified to take the NAPLEX for California (includes score transfers); 1,990 CPJE examinations have been administered and 357 have failed the CPJE examinations. Also, 82 regrades of the CPJE have been performed (resulting in no change in score). The CPJE's pass rate is 85 percent

**Restructure of the Competency Committee**

Ms. Herold stated that last year, the Board of Pharmacy agreed with the recommendation from the Licensing Committee to restructure the Competency Committee. The Competency Committee develops and scores the CPJE. The committee is to be restructured into a two-tier structure – a core committee and a group of item writers. The item writers will develop questions for the examination, and the core committee will select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

To activate this restructuring, the board needs additional pharmacists to serve as item writers and committee members. The board is now aggressively recruiting individuals for these important duties. The board's January 2005 newsletter, (the first since the restructuring was approved) requests interested individuals to submit applications. All board members are asked to assist in recruiting for these positions.

The item writers will meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline will be assigned. There will be no other meeting for this group of individuals.

The core committee will be slightly smaller than the current Competency Committee (if the current Competency Committee was fully appointed, there would be 29 members). The new structure is:

| Composition: | 19 members |
|---|---|
| Schools of Pharmacy: 1 member each | 6 members |
| Community Practice: | 6 members |
| Institutional Practice: | 5 members |
| Board Member: | 1 member |
| Inspector: | 1 member |

Attendance of the core committee meetings will be a requirement, and those who miss a certain number of committee meetings each year will be asked to become item writers, where attendance at meetings is not necessary. There will be six two-day meetings annually.

The preference for members of both committees would be for pharmacists who are more recent graduates of pharmacy schools instead of long-term practicing pharmacists, although some experienced pharmacists are also needed. Newer pharmacists are sought because the examination measures practice at the entry level with two years' pharmacist experience, not after 20 years of experience.

Ms. Herold added that appointment to the committee or as an item writer is an honor and an opportunity to give back to the profession. It is also a good opportunity to learn more about Pharmacy Law. Committee members are paid $30 per hour to perform committee duties.

The board's president appoints the members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814).

**Job Analysis**

Ms. Herold explained that the board is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline. The board completed its last job analysis in 1999/00.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses will be tallied by the board's

examination consultant and analyzed by the Competency Committee in August. A new content outline should be in place by the end of 2005. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

**Administration of the CPJE – New Vendor Contract**

Ms. Herold reported that the board's CPJE is administered through Experior Assessments, LLC, at test centers nationwide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because each agency is not required to go out to bid for separate test administration contracts. However, this master contract ends November 30, 2005.

Currently the Department of Consumer Affairs is preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years.

At this time, the tentative RFP release date is April 4th. Review of the responses to the RFP by the evaluation team will be completed by May 4. The new contact should be awarded on June 20, 2005, leaving four months to implement a transition to the new contract before the end of the current contract.

Delays in this process could impact the ability of applicants to take the CPJE after November 30, 2005. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems in December.

**Petition Process for Intern Hours**

For a number of years, pharmacist interns have been required to earn 1,500 hours of intern experience as a requirement for pharmacist licensure. The only exception was for pharmacists licensed in other states who could meet this requirement by providing evidence of licensure and working as a pharmacist for one year in another state.

Last year's board omnibus bill (SB 1913, Chapter 695) contained provisions that moved key intern requirements from board regulations to statutes. At the January 2005 Board Meeting, the board approved adoption of a related rulemaking to streamline the requirements for earning intern hours. Several changes were made, including one to eliminate a cap of 250 hours on maximum intern hours earned during the first year of pharmacy school. The final version of the regulation follows this memorandum and should be in effect about July 1, 2005.

Since before 1990, the board has had an informal process to allow pharmacists from foreign countries to petition for 600 intern hours for experience they earned in the foreign country as an intern or pharmacist. To petition for the 600 hours, the applicants had to have earned 250 hours of intern experience in California, and provide experience affidavits attesting to their experience in the foreign country. The board used the old intern experience affidavits and required an

estimate of how many hours the applicant spent performing the specific duties in the foreign country.

The core of this evaluation was the assumption that the time spent performing the duties on the experience affidavit in the foreign country (e.g., processing prescriptions) would be the same as when performed in California. There was no other validation for this assessment. Members of the Competency Committee would review these experience petitions. Anyone who worked with the individual from the foreign country could sign the affidavit, although the board preferred that a pharmacist do it. Typically fewer than 10 of these petitions are received annually.

The problem is that the petition process outlined above is an underground regulation, and the board cannot continue with this process unless a regulation is promulgated to permit it. The committee did not take any action on this item.

**Accreditation Council for Pharmacy Education (ACPE) Site Visits**

Over the last few months, the ACPE has visited the new schools of pharmacy at Loma Linda University and the University of California San Diego. Chairperson Conroy participated in the review at the Loma Linda School of Pharmacy, and Board Member Schell participated in the review at UCSD. It was noted that Board Member Dave Fong would be participating in the pre-candidate review at the University of Touro in April.

**Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients**

At the last Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide the foundation to begin the discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and the independent practice of pharmacists as health care professionals.

The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner than later as the provisions of the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

To educate the Licensing Committee on some the initiatives being considered in other states, Nevin Okay from Medco Health Solutions, Inc. presented its alternative pharmacy practice site model. This model allows a pharmacist to practice pharmacy from his/her home under the

auspices of a single pharmacy permit for Medco Pharmacy. It was noted that current CA pharmacy law allows this practice.

Based on the questions discussed at the last meeting, staff drafted a proposal from which the committee could begin addressing the many issues. It was explained the proposal is a means by which to begin the discussions. For better understanding, the concepts were written as statutory changes. The proposal updates: the definition of a pharmacist, the definition of a pharmacy to include an "intake/dispensing pharmacy," a "prescription processing pharmacy," an "advice/clinical care pharmacy" and "nonresident pharmacy" and acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.

The proposal also updates pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist. It also requires that a pharmacist who performs cognitive services for California patients be licensed in California. Additionally, it specifies that a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Statutory changes were also made to the pharmacist scope of practice sections, which are technical, clean up to make the statutes easier to read and understand. These sections provide for pharmacists' collaborative practice with a physician pursuant to a protocol. There is no change to the scope of practice for pharmacists, the protocol or the emergency contraception drug therapy requirements.

Other changes updated the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Requires that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

In addition, there is a change to require a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management. The board is also given authority to investigate matters related to the performance or provision of cognitive services. The definition of unprofessional conduct for a pharmacist is amended to include those acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services. It also includes the acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct may include acts or omissions that involve the failure

to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

There was considerable discussion and concern expressed regarding the draft statutory proposal. The greatest concern raised was the requirement that pharmacists practicing outside of California and providing cognitive services to California patients would be required to be licensed pharmacists in California. Another concern was the proposed requirement that the pharmacist-in-charge for nonresident pharmacies would be required to be licensed California pharmacists. There were also questions as to the expanded definitions of pharmacy and the need for these types of facilities to be licensed as pharmacies. It was noted that the proposal was comprehensive, complex and overwhelming. Chair Ruth Conroy explained that the proposal would be the focus of roundtable discussions at future Licensing Committee meetings.

Chair Conroy summarized the issues that the proposal was addressing.

**Issue 1**
This issue addressed the central processing of prescriptions by California licensed pharmacies. In this situation, Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

In this situation, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

The Licensing Committee didn't have an issue with this situation.

**Issue 2**
In this example, a prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that

may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

The central processing facility would fit the definition of proposed Business and Professions Code section 4037(a)(2). It would be considered a prescription processing pharmacy.

**Issue 3**

This scenario is related to a prescription that originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

It was noted that the out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

The proposal would require that this pharmacy be licensed as a "nonresident pharmacy" and would require that the pharmacist-in-charge and the pharmacists performing drug utilization review and/or any other cognitive pharmacy services for California patients be licensed as well.

**Issue 4**

The fourth example that was presented was about a database for California pharmacies that is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

For this scenario, the out-of-state pharmacy would be required to be licensed in California as a non-resident pharmacy. The pharmacist-in-charge and any pharmacists performing cognitive services would also be required to be licensed in California.

**Issue 5**

The last situation is the new provision in the Medicare Modernization Act (MMA) that addresses Pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/monitoring/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacist related services.

It was noted in the comments provided by the National Association of Boards of Pharmacy (NABP) to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, that NABP was not clear on how states will view the provision of MTMP's across state lines.

The proposal amends Business and Professions Code section 4051, updating the authority and responsibility of pharmacists performing functions related to the practice of pharmacy so as to encompass many of the MTM services. The proposal also requires that a pharmacist performing these functions for California patients be licensed in California. This section of law currently authorizes a pharmacist outside of a licensed pharmacy to provide cognitive services, clinical advice or information and patient consultation.

**Adjournment**

Licensing Committee Chair Ruth Conroy adjourned the meeting at 12:30 p.m.

# Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

| | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **APPLICATIONS** | | | | | | | | | | | | | |
| Received | | | | | | | | | | | | | |
| Pharmacist (exam applications) | 139 | 109 | 121 | 109 | 76 | 88 | 59 | 45 | | | | | 746 |
| Pharmacist (initial licensing applications) | 265 | 233 | 285 | 156 | 112 | 83 | 27 | 8 | | | | | 1169 |
| Intern pharmacist | 59 | 257 | 417 | 363 | 101 | 94 | 21 | 50 | | | | | 1362 |
| Pharmacy technician | 453 | 525 | 647 | 534 | 355 | 542 | 559 | 436 | | | | | 4051 |
| Foreign educated pharmacists (evaluations) | 11 | 57 | n/a | n/a | n/a | n/a | n/a | n/a | | | | | 68 |
| Pharmacy | 27 | 41 | 32 | 34 | 26 | 20 | 23 | 31 | 24 | | | | 258 |
| Sterile Compounding | 4 | 12 | 4 | 4 | 4 | 6 | 5 | 0 | 8 | | | | 47 |
| Clinics | 28 | 21 | 13 | 8 | 10 | 9 | 10 | 2 | 9 | | | | 110 |
| Hospitals | 5 | 2 | 6 | 10 | 3 | 2 | | | 0 | | | | 28 |
| Nonresident Pharmacy | 8 | 9 | 3 | 10 | 2 | 4 | 9 | 7 | 11 | | | | 63 |
| Licensed Correctional Facility | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | 0 |
| Hypodermic Needle and Syringes | 2 | 2 | 5 | 4 | 0 | 2 | 1 | 2 | 1 | | | | 19 |
| Out of State Distributor | 11 | 11 | 8 | 5 | 3 | 15 | 10 | 10 | 9 | | | | 82 |
| Wholesalers | 8 | 5 | 6 | 2 | 9 | 23 | 7 | 0 | 6 | | | | 66 |
| Veterinary Food-Animal Drug Retailer | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | | | 1 |
| Exemptees | 55 | 29 | 56 | 40 | 33 | 18 | 26 | 43 | 9 | | | | 309 |
| Issued | | | | | | | | | | | | | |
| Pharmacist | 307 | 229 | 226 | 169 | 129 | 91 | 34 | 8 | | | | | 1193 |
| Intern pharmacist | 63 | 178 | 226 | 274 | 230 | 73 | 93 | 38 | | | | | 1175 |
| Pharmacy technician | 672 | 408 | 663 | 506 | 353 | 233 | 670 | 528 | | | | | 4033 |
| Pharmacy | 28 | 36 | 49 | 23 | 20 | 23 | 32 | 21 | 35 | | | | 267 |
| Sterile Compounding | 4 | 7 | 2 | 5 | 4 | 3 | 5 | 2 | 3 | | | | 35 |
| Clinics | 15 | 15 | 23 | 15 | 7 | 7 | 6 | 5 | 13 | | | | 106 |
| Hospitals | 4 | 2 | 2 | 2 | 3 | 2 | 6 | 0 | 5 | | | | 26 |
| Nonresident Pharmacy | 4 | 4 | 3 | 5 | 4 | 7 | 0 | 7 | 8 | | | | 42 |
| Licensed Correctional Facility | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | 0 |
| Hypodermic Needle and Syringes | 7 | 2 | 3 | 0 | 5 | 2 | 1 | 4 | 0 | | | | 24 |
| Out of State Distributor | 4 | 13 | 8 | 7 | 8 | 14 | 1 | 6 | 1 | | | | 62 |
| Wholesalers | 6 | 5 | 14 | 1 | 7 | 6 | 8 | 3 | 2 | | | | 52 |
| Veterinary Food-Animal Drug Retailer | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | 3 |
| Exemptees | 42 | 52 | 28 | 45 | 38 | 26 | 33 | 17 | 42 | | | | 323 |

# Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

| | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pending | | | | | | | | | | | | | |
| Pharmacist Examination | 200 | 76 | 69 | 179 | 101 | 47 | 35 | 69 | 58 | | | | 47 |
| Intern pharmacist | u/a | u/a | 83 | u/a | u/a | 66 | u/a | u/a | 141 | | | | 66 |
| Pharmacy technician | u/a | u/a | u/a | u/a | u/a | u/a | u/a | u/a | u/a | | | | u/a |
| Foreign educated pharmacists (evaluations) | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | | | | n/a |
| Pharmacy | 71 | 69 | 52 | 63 | 69 | 60 | 50 | 60 | 49 | | | | 49 |
| Sterile Compounding | 43 | 48 | 50 | 49 | 49 | 48 | 48 | 46 | 51 | | | | 51 |
| Clinics | 61 | 67 | 57 | 50 | 53 | 60 | 64 | 61 | 57 | | | | 57 |
| Hospitals | 10 | 8 | 12 | 20 | 20 | 20 | 15 | 15 | 10 | | | | 10 |
| Nonresident Pharmacy | 33 | 29 | 29 | 34 | 32 | 33 | 42 | 42 | 45 | | | | 45 |
| Licensed Correctional Facility | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | 0 |
| Hypodermic Needle and Syringes | 3 | 3 | 5 | 9 | 4 | 5 | 5 | 3 | 4 | | | | 4 |
| Out of State Distributor | 47 | 45 | 50 | 48 | 43 | 50 | 59 | 63 | 71 | | | | 71 |
| Wholesalers | 27 | 27 | 19 | 20 | 22 | 39 | 38 | 35 | 39 | | | | 39 |
| Veterinary Food-Animal Drug Retailer | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | | | | 1 |
| Exemptees | 180 | 157 | 185 | 97* | 92 | 87 | 80 | 106 | 73 | | | | 73 |
| Change of Pharmacist-in-Charge | | | | | | | | | | | | | |
| Received | 183 | 229 | 156 | 151 | 122 | 111 | 98 | 91 | 210 | | | | 1351 |
| Processed | 141 | 175 | 105 | 164 | 119 | 112 | 174 | 123 | 68 | | | | 1181 |
| Pending | 214 | 268 | 319 | 306 | 309 | 308 | 232 | 200 | 342 | | | | 342 |
| Change of Exemptee-in-Charge | | | | | | | | | | | | | |
| Received | 4 | 4 | 3 | 3 | 3 | 1 | 3 | 6 | 16 | | | | 43 |
| Processed | 4 | 5 | 3 | 1 | 3 | 1 | 3 | 4 | 9 | | | | 33 |
| Pending | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 9 | | | | 9 |
| Change of Permits | | | | | | | | | | | | | |
| Received | 30 | 86 | 60 | 61 | 60 | 44 | 44 | 81 | 75 | | | | 541 |
| Processed | 24 | 69 | 49 | 90 | 61 | 68 | 41 | 53 | 60 | | | | 515 |
| Pending | 139 | 156 | 167 | 138 | 137 | 113 | 116 | 144 | 159 | | | | 159 |
| Discontinuance of Business | | | | | | | | | | | | | |
| Received | 11 | 15 | 17 | 18 | 14 | 13 | 12 | 18 | 23 | | | | 141 |
| Processed | 0 | 26 | 0 | 25 | 1 | 35 | 0 | 29 | 12 | | | | 128 |
| Pending | 16 | 21 | 38 | 31 | 44 | 22 | 34 | 23 | 34 | | | | 34 |

# Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

| | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Renewals Received | | | | | | | | | | | | | |
| Pharmacist | 1031 | 3278 | 1249 | 1182 | 1067 | 1149 | 1170 | 1132 | | | | | 11258 |
| Pharmacy technician | 1339 | 3089 | 1763 | 1692 | 1529 | 1529 | 1608 | 1508 | | | | | 14057 |
| Pharmacy | 652 | 609 | 862 | 508 | 284 | 283 | 392 | 576 | | | | | 4166 |
| Sterile Compounding | 12 | 12 | 11 | 22 | 4 | 5 | 12 | 11 | | | | | 89 |
| Clinics | 49 | 149 | 55 | 50 | 49 | 53 | 71 | 57 | | | | | 533 |
| Nonresident Pharmacy | 19 | 32 | 11 | 18 | 4 | 20 | 17 | 10 | | | | | 131 |
| Hypodermic Needle and Syringes | 16 | 18 | 21 | 22 | 18 | 28 | 25 | 19 | | | | | 167 |
| Out of State Distributor | 18 | 56 | 22 | 23 | 20 | 20 | 28 | 13 | | | | | 200 |
| Wholesalers | 28 | 98 | 22 | 37 | 28 | 36 | 42 | 28 | | | | | 319 |
| Veterinary Food-Animal Drug Retailer | 1 | 5 | 1 | 2 | 0 | 2 | 0 | 2 | | | | | 13 |
| Exemptees | 113 | 348 | 119 | 122 | 126 | 155 | 165 | 132 | | | | | 1280 |

*hand count

# ATTACHMENT C

# Licensing Committee

**2004-2005**
**Third Quarter Report**
**January 1, 2005 – March 31, 2005**

**Goal 2:** **Ensure the professional qualifications of licensees.**

**Outcome:** **Qualified licensees.**

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**Objective 2.1:** **Issue licenses within three working days of a completed application by June 30, 2005.**

**Measures:** **Percentage of licenses issued within 3 working days.**

*A new tracking system has been implemented.*

**Tasks:**

1. **Review 100 percent of all applications within 7 working days of receipt.**

   *Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.*

| | **Apps. Received:** | | | | **Average Days to Process:** | | | |
|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Pharmacist (exam applications) | 369 | 273* | 104** | | 23 | 24 | 14 | |
| Pharmacist (initial licensing) | 783 | 351* | 35** | | 3 | 7 | 3.6 | |
| Pharmacy Intern | 733 | 558* | 71** | | 10 | 7 | 10 | |
| Pharmacy Technicians | 1625 | 1431* | 995** | | 5-10 | 15-20 | 15-20 | |
| Foreign Graduates | | | | | | | | |
| Pharmacies | 100 | 95 | 78 | | 6 | 9 | 9 | |
| Non-Resident Pharmacy | 20 | 16 | 27 | | 22 | 16 | 21 | |
| Wholesaler | 19 | 34 | 13 | | 39 | 4 | 11 | |
| Veterinary Drug Retailer | 0 | 1 | 0 | | 0 | 0 | 13 | |
| Exemptee | 140 | 91 | 78 | | 8 | 12 | 7 | |
| Out-of-State Distributor | 30 | 23 | 29 | | 7 | 18 | 11 | |
| Clinics | 62 | 27 | 21 | | 7 | 6 | 11 | |
| Hypo Needle & Syringe | 9 | 6 | 4 | | 1 | 8 | 9 | |
| Sterile Compounding | 20 | 14 | 14 | | 2 | 4 | 10 | |

* Denotes December 2004 information has been added since the Second Quarter report.
**Denotes January and February 2005 information available at time of report development.

2. **Process 100 percent of all deficiency documents within 3 working days of receipt.**

Average days to process deficiency:

| | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| Pharmacist (exam applications) | 3-7 | 5-10 | 5-10 | |
| Pharmacist (initial licensing) | 3-7 | 5-10 | 5-7 | |
| Pharmacy Intern | 10 | 7 | 7 | |
| Pharmacy Technicians | 5-7 | 7 | 7 | |
| Foreign Graduates | N/A | N/A | N/A | |
| Pharmacies | 9 | 3 | 3 | |
| Non-Resident Pharmacy | 10 | 1 | 0 | |
| Wholesaler | 9 | 8 | 3 | |
| Veterinary Drug Retailer | 0 | 0 | 1 | |
| Exemptee | 3 | 4 | 3 | |
| Out-of-State Distributor | 11 | 10 | 2 | |
| Clinics | 7 | 2 | 2 | |
| Hypo Needle & Syringe | 5 | 1 | 1 | |

3. **Make a licensing decision within 3 working days after all deficiencies are corrected.**

Average days to issue license:

| | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| Pharmacist (exam applications) | 1-2 | 1-2 | 1-2 | |
| Pharmacist (initial licensing) | 1-2 | 1-2 | 1-2 | |
| Pharmacy Intern | 5 | 3-5 | 3-5 | |
| Pharmacy Technicians | 5 | 5 | 5 | |
| | | | | |
| Pharmacies | 4 | 2 | 1 | |
| Non-Resident Pharmacy | 3 | 1 | 2 | |
| Wholesaler | 3 | 3 | 1 | |
| Veterinary Drug Retailer | 0 | 0 | 13 | |
| Exemptee | 2 | 12 | 10 | |
| Out-of-State Distributor | 4 | 3 | 17 | |
| Clinics | 4 | 1 | 1 | |
| Hypo Needle & Syringe | 6 | 1 | 5 | |

4. **Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.**

| | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| Pharmacist | 762 | 389 | 42* | |
| Pharmacy Intern | 467 | 577 | 131* | |
| Pharmacy Technician | 1743 | 1092 | 1198* | |
| Foreign Graduate | N/A | N/A | N/A | |
| Pharmacies | 121 | 79 | 99 | |
| Non-Resident Pharmacy | 11 | 10 | 15 | |
| Wholesaler | 25 | 14 | 13 | |
| Veterinary Drug Retailer | 3 | 0 | 0 | |
| Exemptee | 122 | 106 | 92 | |
| Out-of-State Distributor | 25 | 23 | 8 | |
| Clinics | 53 | 24 | 24 | |
| Hypo Needle & Syringe | 12 | 6 | 5 | |
| Sterile Compounding | 13 | 16 | 10 | |
| * Denotes January and February 2005 information available at time of report. | | | | |

5. **Withdrawn licenses to applicants not meeting board requirements.**

| | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| Pharmacy Technician | 11 | 0 | 10 | |
| Pharmacies | 15 | 1 | 1 | |
| Non-Resident Pharmacy | 13 | 1 | 7 | |
| Clinics | 28 | 3 | 11 | |
| Sterile Compounding | 2 | 5 | 0 | |
| Exemptees | 0 | 32 | 8 | |
| Hypo Needle & Syringe | 0 | 3 | 2 | |
| Out-of-State Distributor | 0 | 8 | 9 | |
| Wholesaler | 0 | 4 | 4 | |

**Objective 2.2:** **Implement at least 50 changes to improve licensing decisions by June 30, 2005.**

**Measure:** **Number of implemented changes.**

**Tasks:**

1. **Review Pharmacist Intern Program.**

***9/04*** *Governor signed SB 1913 that contained new intern provisions to become effective 1/05.*

***9/04*** *Licensing Committee recommended changes to 1728 to implement SB 1913.*

*9/04* *Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.*

*9/04* *Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*

*12/04* *Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*

**2. Implement changes to the Pharmacy Technician Program.**

*1/04* *a. Use PTCB as a qualifying method for registration. – Completed.*

*1/04* *b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology. – Completed.*

*9/04* *c. Eliminate clerk-typist from pharmacist supervisory ratio. Completed – regulation approved by OAL, change effective 10/3/04.*

*9/04* *Enforcement Committee recommended technical changes to the regulatory requirements for pharmacy technicians.*

*10/04* *Board approved the recommendation and will sponsor legislation in 2005.*

*3/05* *SB 1111 (B&P Committee) was introduced.*

**3. Administer a pharmacist licensure exam more than twice a year.**

*3/04* *Completed – CA applications began taking the NAPLEX and CPJE.*

*9/04* *826 California applicants have taken the NAPLEX and 1,006 have taken the CPJE since July 1, 2004.*

*1/05* *1,240 California applicants have taken the NAPLEX and 1,335 have taken the CPJE since July 1, 2004.*

*4/05* *1,450 California applicants have taken the NAPLEX and 1,648 have taken the CPJE since July 1, 2004.*

**4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.**

5. **Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.**

6. **Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.**

***8/04*** *Competency Committee met for two days and developed questions as well as the job analysis.*

***9/04*** *Competency Committee met for two days and developed questions.*

***9/04*** *Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).*

***10/04*** *Competency Committee met for two days and developed questions.*

***11/04*** *Job analysis will be released.*

***12/04*** *Job analysis released to 3,000 pharmacists.*

***1/05*** *Competency Committee met for two days and developed questions.*

***205*** *Competency Committee met for two days and developed questions.*

***4/05*** *Competency Committee met for two days and developed questions.*

7. **Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.**

***6/04*** *Completed*

***9/04*** *OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.*

***9/04*** *Reported that 13 sterile compounding licensed have been issued since July 1, 2004.*

***1/05*** *Reported that 29 sterile compounding licenses have been issued since July 1, 2004.*

8. **Issue temporary permits whenever change of ownership occurs.**

***9/04*** *1st Quarter – 22 temporary permits issued.*

***1/05*** *2nd Quarter – 29 temporary permits issued.*

*4/05* *3rd Quarter – 29 temporary permits issued.*

**9. Establish means for licensee to renew permits on line.**

*8/04* *Submitted Applicant Tracking System (ATS) report to the department.*

*11/04* *Met with the department to discuss conversion to ATS and department prioritization.*

**10. Implement Changes to Facilities Licensure Requirements**

*9/04* *Governor signed SB 1913 that included application requirements for all applicants.*

*9/04* *Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.*

*9/04* *Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.*

*1/05* *New application forms are available for nonresident wholesalers.*

*1/05* *New application forms are available for wholesalers.*

*2/05* *Initiate review of clinic application requirements.*

*3/05* *Initiate review of community pharmacy application requirements.*

*3/05* *Initiate implementation of the surety bond requirement.*

**11. Review the Ownership of Pharmacies**

*7/04* *Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.*

**12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.**

*7/04* *Draft report provided to the board.*

*9/04* *Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).*

*9/04* *Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.*

*12/04* *Report provided to the Legislature.*

**13. Evaluate application requirements for all licenses.**

***9/04*** *Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.*

***9/04*** *Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).*

***9/04*** *Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.*

***9/04*** *Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

***9/04*** *Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.*

***9/04*** *Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.*

***10/04*** *Board approved statutory proposal to eliminate the rules of professional conducted required for each application and omnibus changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

***12/04*** *Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*

***3/05*** *SB 1111 (B&P) introduced that contains statutory changes to eliminate "Rules of Professional Conduct."*

**14. Review the law regarding the educational requirements of graduates from foreign pharmacy schools.**

***9/04*** *Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.*

***9/04*** *Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*

***9/04*** *Sent a letter to all pending foreign graduates advising of law change and suspending application process.*

***12/04*** *Sent letter to all foreign graduate exam applicants not certified about revised exam eligibility status.*

**15. Review the law regarding continuing education (CE) requirements for pharmacists.**

***7/04*** *Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*

***9/04*** *Licensing Committee recommended changes to the CE statute to relocate from regulation the 30 hour requirement, to exempt all newly licensed pharmacist from CE requirements for two years and to renew the pharmacists license as "inactive" when a pharmacist fails to certify their CE credits.*

***9/04*** *Licensing Committee recommended revisions to the CE regulations.*

***10/04*** *Board approved recommended statutory and regulatory revisions to CE requirements.*

***1/05*** *SB 1111 (B&P) introduced that contains CE provision.*

**16. Review the license of city and county jails and juvenile facilities.**

***8/04*** *Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.*

**17. Review the certification process for foreign graduates that was implemented 1/05 and the Test of Spoken English (TSE requirement).**

***3/05*** *Licensing Committee discussed the certification process and TSE requirement. Requested TSE presentation at future board meeting.*

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| **Objective 2.3:** | **Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.** |
| **Measure:** | **Number of public policy initiatives evaluated.** |
| **Tasks:** | **1. Explore the need to regulate pharmacy benefit managers.** |
| ***10/03*** | *Board concluded not to regulate PBMs.* |
| ***9/04*** | *Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.* |
| | **2. Explore the need to regulate drugs labeled for "veterinary use only."** |
| ***9/03*** | *SB 175 was introduced and signed (Chaptered 250, Statutes 2003).* |
| ***1/04*** | *Completed.* |
| | **3. Explore the importation of drugs from foreign countries.** |
| ***7/04*** | *Discussed at July Board meeting.* |
| ***9/04*** | *Discussed at September Enforcement Committee meeting.* |
| ***9/04*** | *Governor vetoed SB 1449 which would have required the board to approve Web sites for Canadian pharmacies.* |
| ***10/04*** | *Discussed at October board meeting.* |
| ***12/04*** | *Discussed at December Enforcement Committee meeting.* |
| ***12/04*** | *HHS released its report of the Task Force on Drug Importation.* |
| ***1/05*** | *Discussed at January board meeting.* |
| ***3/05*** | *Discussed at March Enforcement Committee Meeting.* |

**4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.**

***9/04*** *OAL approved regulation change and will take effect 10/22.*

***10/04*** *Completed.*

**5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding**

***9/04*** *Held third meeting of workgroup on compounding – proposed draft concept on general compounding.*

***12/04*** *Held forth meeting of workgroup on compounding – recommending statutory proposal.*

***12/04*** *Licensing Committee recommended approval of statutory proposal to define general compounding and regulatory parameters.*

***1/05*** *Board approved general compounding proposal.*

***2//05*** *AB 595 was introduced and sponsored by the board.*

**6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)**

***7/04*** *Protocol on Web site.*

***7/04*** *Board approved regulation on protocol.*

***9/04*** *Regulation submitted to OAL for approval.*

***11/04*** *OAL approved regulation, which became effective 12/04.*

**7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.**

***9/04*** *Governor signed SB 1913 that provides authority.*

**8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.**

***4/04*** *Board approved waiver for two years.*

**9. Development of Proposal for Pharmacist Performing DUR, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for CA patients.**

***12/04*** *Licensing Committee discussed concepts related to proposal.*

***3/05*** *Licensing Committee discussed draft and proposal.*

| | |
|---|---|
| **Objective 2.4:** | **Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.** |
| **Measure:** | **Percentage of cashiered application and renewal fees within 2 working days.** |
| **Tasks:** | **1. Cashier application fees.** |
| ***9/04*** | *1st Quarter - The average processing time for processing new application fees is 2-3 working days.* |
| ***1/05*** | *2nd Quarter - The average processing time for processing new application fees is 2-3 working days.* |
| ***4/05*** | *3rd Quarter - The average processing time for processing new application fees is 2-3 working days.* |
| | **2. Cashier renewal fees.** |
| ***9/03*** | *The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.* |
| ***8/04*** | *Held interviews for renewal cashier because hiring freeze was lifted.* |
| ***9/04*** | *1st Quarter - Average processing time for central cashiering is 2-3 weeks.* |
| ***10/04*** | *Filled vacancy for renewal cashier.* |
| ***1/05*** | *2nd Quarter – Average processing time for central cashiering is 1-2 weeks.* |
| ***4/05*** | *3rd Quarter – Average processing time for central cashiering is 1-2 weeks.* |
| **Objective 2.5:** | **Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.** |
| **Measure:** | **Percentage response for verifying licensing information within 5 working days.** |
| **Tasks:** | **1. Respond to requests for licensing verification.** |
| ***9/04*** | *1st Quarter – Processed 227 license verifications.* |
| ***1/05*** | *2nd Quarter – Processed 208 license verifications.* |
| ***4/05*** | *3rd Quarter – Processed 198 license verifications.* |

| | |
|---|---|
| **Objective 2.6:** | **Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.** |
| **Measure:** | **Percentage of licensing records changes within 5 working days** |

**Tasks:**

**1. Make address and name changes.**

***9/04*** *1st Quarter – Processed 2,478 address changes.*

***1/05*** *2nd Quarter – Processed 1, 557 address changes.*

***4/05*** *3rd Quarter – Processed 1,848 address changes.*

**2. Process discontinuance of businesses forms and related components.**

***9/04*** *1st Quarter – Processed 26 discontinuance- of-business forms. Processing time is 44 days.*

***1/05*** *2nd Quarter – Processed 61 discontinuance- of-business forms. Processing time is 40 days.*

***4/05*** *3rd Quarter – Processed 44 discontinuance- of-business forms. Processing time is 19 days.*

**3. Process changes in pharmacist-in-charge and exemptee-in-charge.**

***9/04*** *1st Quarter – Processed 421 pharmacist-in-charge changes. Average processing time is 23 days. Processed 12 exemptee-in-charge changes. The average processing time is 2 days.*

***1/05*** *2nd Quarter – Processed 395 pharmacist-in-charge changes. Average processing time is 25 days. Processed 6 exemptee-in-charge changes. The average processing time is 2 days.*

***4/05*** *3rd Quarter – Processed 365 pharmacist-in-charge changes. Average processing time is 15 days. Processed 16 exemptee-in-charge changes. The average processing time is 5 days.*

**4. Process off-site storage applications.**

***9/04*** *Processed 33 off-site storage applications.*

***1/05*** *Processed 15 off-site storage applications.*

***4/05*** *Processed 20 off-site storage applications.*

**5. Process change-of-permit applications.**

| | |
|---|---|
| ***9/04*** | *1st Quarter – Processed 142 applications. Average processing time is 25 days.* |
| ***1/05*** | *2nd Quarter – Processed 219 applications. Average processing time is 15 days.* |
| ***4/05*** | *3rd Quarter – Processed 169 applications. Average processing time is 19 days.* |